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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,234	09/25/2000	Pascal Vannuffel	VANM145.001A	9668

20995 7590 07/03/2002

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EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	19

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/509,234	Applicant(s) VANNUFFEL ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-11,13-23 and 31-42* is/are pending in the application.

4a) Of the above claim(s) *6,15-23 and 34-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,7-11,13,14 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Applicant's election with traverse of Group I, SEQ ID NO: 1 in Paper No. 18 is acknowledged. The traversal is on the ground(s) that the groups are directed to subject matter that is closely interrelated and therefore examination of all of the groups would not place an undue burden on the Examiner. Applicants point out that the nucleic acid sequence of SEQ ID NO: 1 is a consensus sequence resulting from the alignment of Staphylococcus femA nucleotide sequences and assert that undue burden would not be required to further examine SEQ ID NO: 2-39, 40, 42, 44, and 56-64. This is not found persuasive because, in the absence of evidence to the contrary, each of the claimed nucleotide sequences is considered to be unobvious over each other. Each of the claimed sequences consists of a distinct nucleotide sequence and each have different functional properties in that they are specific for different species of Staphylococcus. The sequence of SEQ ID NO: 1 is considered to be distinct from the naturally occurring sequences of 2-39, 40, 42, 44, 54 and 56-64 because SEQ ID NO: 1 represents a consensus sequence derived by comparing each of these individual sequences. A search of the stated 55 nucleotide sequences, and all subfragments of these sequences of at least 15 nucleotides, together with a search of SEQ ID NO: 1 and subfragments thereof would be undue burden because these searches are not co-extensive, but rather require a separate search of each of the nucleotide sequence. Accordingly, the requirement is still deemed proper and is therefore made FINAL.

It is noted that claims 6, 15-23 and 34-42 are withdrawn from consideration as being drawn to a non-elected invention.

2. The specification is objected to because the assigned SEQ ID NOs have not been used to identify each sequence listed, as required under 37 CFR §1.821(d). See, **for example**, pages 8-10 and 17-19 of the specification.

3. The drawings filed in this application have been approved by the Draftsman.

4. Claim 7-11, 13, 14, 32 and 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-11, 13, 14, 32 and 33 are indefinite because it is not clear as to whether the claims are drawn to 2 or more oligonucleotides wherein each oligonucleotide is distinct from the others or whether the claims are drawn to multiple copies of the same oligonucleotide. Furthermore, since the claims recite two or more oligonucleotides in which one of the oligonucleotides may comprise a sequence having 60% identity with SEQ ID NO: 1 **and/or** one oligonucleotide may comprise a sequence having at least 60% identity with SEQ ID NO: 1, 46, 48, 50 or 52, in claims 8-10 it is unclear as to whether the oligonucleotides must share 70-90% identity with stated sequences or with only one of the stated sequences. With respect to claim 11, as discussed above, it is unclear as to whether the "more than 2 oligonucleotides" must include, for example, both SEQ ID NO: 1 and 18 or may include SEQ ID NO: 1 and any other oligonucleotide, or may include multiple copies of SEQ ID NO: 1. It is also unclear as to whether each of the oligonucleotides in the "two or more oligonucleotides" have the stated identity to SEQ ID NO: 1 or whether one of the oligonucleotides has the stated identity with SEQ ID NO: 1

and at least one of the other oligonucleotides has the stated identity with the **complement** of SEQ ID NO: 1.

Claim 33 is indefinite over the recitation of "media" because in the context of the claim, it is unclear as to what media is intended to encompass. While "media" generally refers to substances on which to grow an organism or a means of communication, it is unclear as to what is meant by media necessary to perform the stated DNA diagnostic methods. This rejection may be overcome by amendment of the claim to recite, for example, "reagents". It is also unclear as to what is intended to be encompassed by **all** the media required to perform the stated methods. For example, for the Southern blot analysis, does this mean that the "diagnostic device" includes, buffers, electrophoresis gel, electrophoresis apparatus, filters, blotting solutions and set-up, etc. Clarification of the claim is required.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 7-10, 13, 14, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Unal (Journal of Clinical Microbiology (1992) 30:1685-1691; cited in the IDS of Paper No. 6).

Unal et al (page 1686) teaches primers for amplifying the femA gene of Staphylococcus. The primers include: a) a 23-mer forward primer which is 100% homologous to nucleotides 765-786 of SEQ ID NO: 1; and b) a 19-mer reverse primer which is 95% complementary to nucleotides 1735-1753 of SEQ ID NO: 1. Accordingly, Unal teaches oligonucleotides comprising 15 to 350 or 17 to 250 nucleotides of SEQ ID NO: 1. The primers of Unal are also considered to be a diagnostic device for identifying Staphylococci species. Furthermore, Unal teaches methods for detecting Staphylococcus wherein the methods comprise amplifying sample nucleic acids using said primers, separating the amplification products by gel electrophoresis and detecting the amplification products and the size of the amplification products as indicative of the presence of Staphylococcus (see page 1688). Unal also teaches that the femA gene can be detected using a hybridization probe (pages 1688-1689).

6. Claims 1, 2, 5, 7-11, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Alborn et al (EP 0625575 A2; cited in the IDS of Paper No. 6).

Alborn et al (pages 4-6) teaches a Staphylococcus epidermidis femA nucleotide sequence which comprises sequences of 15-350, 17-250 or 17-25 nucleotides having 100% identity with instant SEQ ID NO: 1. With respect to claims 7-11, the claims have been interpreted as including multiple copies of the same oligonucleotide and Alborn teaches compositions comprising multiple copies of the femA nucleic acids. The nucleic acid of Alborn is also considered to be a diagnostic device for identifying Staphylococci species.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Unal in view of the Stratagene Catalog.

Unal et al (page 1686) teaches primers for amplifying the femA gene of Staphylococcus. The primers include: a) a 23-mer forward primer which is 100% homologous to nucleotides 765-786 of SEQ ID NO: 1; and b) a 19-mer reverse primer which is 95% complementary to nucleotides 1735-1753 of SEQ ID NO: 1. Accordingly, Unal teaches oligonucleotides comprising 15 to 350 or 17 to 250 nucleotides of SEQ ID NO: 1. The primers of Unal are also considered to be a diagnostic device for identifying Staphylococci species. Furthermore, Unal

teaches methods for detecting Staphylococcus wherein the methods comprise amplifying sample nucleic acids using said primers, separating the amplification products by gel electrophoresis and detecting the amplification products and the size of the amplification products as indicative of the presence of Staphylococcus (see page 1688). Unal also teaches that the femA gene can be detected using a hybridization probe (pages 1688-1689). While Unal teaches the reagents for the detection of amplification products, Unal does not teach a "diagnostic device" or kit comprising the primers and the reagents necessary for detection of amplification products.

However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. In particular, the Stratagene catalog discloses the general concept of kits for performing nucleic acid hybridization methods and discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatibility of the reagents to be used in the assay. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers and reagents for detecting amplification products of Unal in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect Staphylococcus femA nucleic acids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Pauline Farrier whose telephone number is (703) 305-3550.

Carla Myers

June 26, 2002

CARLA J. MYERS
PRIMARY EXAMINER